

REMARKS

Amendments

Specification: Page 1 of the specification has been amended to include a cross-reference to US provisional application No. 60/252,588 filed November 24, 2000, of which the instant application claims benefit. Kindly note that a Petition for an unintentionally delayed domestic priority claim, together with the prescribed statement and fee, is being submitted concurrently herewith.

Claims: There are now 30 claims in the application. Claim 25 has been amended, without prejudice or disclaimer, to recite “wherein said implant is dehydrated or lyophilized prior to implantation” (rather than “wherein said matrix layer is dehydrated or lyophilized prior to implantation”). This amendment finds support at for example page 12 of the specification as well as the working examples of the application. Minor amendments have been made to claims 25, 33, 34, 38, 39, 43, 44 and 50 for clarity. New claims 53 and 54 have been added which are similar in structure to claims 43 and 44.

No new matter has been added by way of these amendments. Applicants reserve the right to pursue any subject matter removed by these amendments in one or more divisional and/or continuation applications.

Concerning 35 USC § 102(e)

The Examiner has rejected claims 25-52 as being allegedly anticipated by Altman (US Patent No. 6,287,340). For the reasons presented below, Applicants respectfully traverse the Examiner’s rejection, and submit that independent claim 25, as it currently stands, is in allowable form.

For ease of reference, the Examiner’s attention is respectfully directed to independent claim 25, and the particular sections shown in bold:

A method of preparing an implant for connective tissue substitution in an animal, said method comprising the steps of:

- (a) providing a pair of bone anchors joined at their proximal ends by at least one support filament, said bone anchors having been joined with said support filament *ex vivo*; and

- (b) incubating said pair of bone anchors in a solution containing matrix forming molecules for a period time sufficient for the formation of **at least one matrix layer around said support filament;**

wherein said matrix layer is of sufficient thickness to allow for colonization by cells, and wherein said **implant is dehydrated or lyophilized** prior to implantation.

As noted in Applicants' letter of April 5, 2005, the Examiner is of the view that certain elements of instant claim 25 are allegedly analogous to certain subject matter disclosed in Altman, as follows:

Element of instant claim 25	Alleged analogous subject matter disclosed in Altman
"support filament"	"cylindrical 3-dimensional matrix formed of collagen gel"
"matrix"	"laminin, fibronectin, or factors containing..."

Firstly, the Examiner argues that Altman discloses that "the matrix and the bone anchor are coated with materials such as laminin, fibronectin, or factors containing arginine-glycine aspartate peptides...". Applicant respectfully disagrees, and respectfully refers to the relevant paragraph of Altman, spanning lines 37 to 50 of column 5:

"Alternatively, anchor material may be created or further enhanced by infusing a selected material with a factor which promotes matrix binding. The term infuse is considered to include any method of application which appropriately distributes the factor onto the anchor (e.g. coating, permeating, contacting). Examples of such factors include without limitation, laminin, fibronectin, any extracellular matrix protein that promotes adhesion, silk, factors which contain arginine-glycine-aspartate peptide binding regions. Growth factors or bone morphogenic protein can also be used to enhance anchor attachment. In addition, anchors may be pre-seeded with cells (e.g. stem cells, ligament cells, osteoblasts) which adhere to the anchors and bind the matrix, to produce enhanced matrix attachment." (emphasis added)

Applicants respectfully submit that the disclosure in Altman of "laminin, fibronectin...", is clearly and in all cases limited only as a possible coating of the anchor material, i.e., not as a possible coating of the analogous matrix material. Indeed, if the interpretation summarized in the above table were true, Altman would need to disclose that "laminin, fibronectin..." may possibly coat the "cylindrical 3-dimensional matrix formed of collagen gel", which is clearly not the case as shown in the above passage from Altman. Applicant therefore respectfully submits that Altman does not disclose an analogous "support

filament” and “matrix” in the same relationship (i.e., the latter formed as a layer around the former) as that recited in instant claim 25.

Secondly, the Examiner argues that “Altman specifically discloses a ‘dehydrothermal’ process that includes dehydration”. For ease of reference, Applicant respectfully refers to the relevant paragraph of Altman, spanning the bottom of column 4 to the top of column 5:

“The matrix used in the examples disclosed herein was a collagen gel. One of skill in the art will recognize that the properties of the preliminary matrix can be modulated and enhanced by modifying the matrix components, and that use of an enhanced matrix is likely to increase the efficiency of production of a bioengineered ACL. Such modifications include, without limitation, modifications aimed at modulating the mechanical and mass transport properties of the matrix. In particular, the concentration of collagen and the degree of crosslinking of collagen in the matrix can significantly influence the mechanical properties of the matrix, as well as the diffusional transport rates of nutrients and large molecules. Since the ACL is made primarily of collagen type I, it is particularly well suited for use as a preliminary matrix component. The concentration of collagen type I in the matrix should be sufficient to support cell adhesion, proliferation and differentiation. In one embodiment, collagen type I is used at a final concentration from about 2 mg/ml to about 6 mg/ml. In another embodiment the final concentration of collagen type I in the matrix is about 2 mg/ml. In another embodiment, the collagen in the preliminary matrix is crosslinked. Suitable processes for cross linking collagen include without limitation, **dehydrothermal** crosslinking and ultraviolet irradiation crosslinking. Other suitable matrix materials include, without limitation polysaccharides, alginates, other proteins such as silk and elastin, synthetic polymers such as polyglycolic acid and polylactic acid and copolymers of the two, and demineralized bone. (emphasis added)

Based on the above passage, Applicant respectfully submits Altman discloses such “dehydrothermal” treatment only with respect to Altman’s “matrix”. In contrast, claim 25 as amended recites that the “implant is dehydrated or lyophilized”, i.e., the implant comprising bone anchors, a support filament and a matrix layer as recited in current claim 25. As such, Altman does not disclose dehydration or lyophilization of a structure other than a collagen matrix, (e.g. dehydration or lyophilization of a structure comprising an anchor is not mentioned), and thus differs from instant claim 25 accordingly.

Thirdly, as per the table above, it is Applicants’ understanding that the Examiner has interpreted that the “matrix” of claim 25 is analogous to “laminin, fibronectin...” of Altman. However, Applicants respectfully submit that Altman does not disclose any dehydrothermal

treatment of “laminin, fibronectin...”. Rather, Altman only discloses such possible treatment of its collagen gel matrix as seen in the above passage, which, as per the above table, has been considered analogous to the “support filament” of instant claim 25. Therefore, under the above interpretation, Altman does not disclose any such treatment in respect of the “matrix” or “anchor” of instant claim 25. As such, Applicants respectfully submit that Altman differs yet further from instant claim 25 as amended.

As per §2131 of the MPEP, in order “to anticipate a claim, the reference must teach every element of the claim”. Since Altman does not teach every element of independent claim 25 as amended, Applicants respectfully submit that claim 25 as amended is novel over Altman. The remaining claims, which depend directly or indirectly from claim 25 and thus incorporate its subject matter therein, are also novel over Altman. In view of the foregoing, reconsideration and withdrawal of the rejection is respectfully requested.

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It is believed that the foregoing responds to all of the Examiner's concerns, however if the Examiner has any further questions, he is invited to contact the undersigned. The timely issuance of a Notice of Allowance is respectfully requested. Further, if the Examiner does not consider that the application is in a form for allowance, an interview with the Examiner is respectfully requested.

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Respectfully submitted,

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